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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,144	07/19/2000	Ulrich Mohr	29089/34670A	1600

7590 07/15/2002
James A Flight
Marshall O'Toole Gerstein Murray & Borun
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6402

EXAMINER

SANDALS, WILLIAM O

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/15/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/619,144

Applicant(s)
Mohr et al.

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 17, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 22, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The corrected or substitute drawings were received on May 22, 2002. These drawings are not acceptable, and must be corrected according to the attached draftspersons drawing review, PTO form 948.

Response to Arguments

3. Amendments to the specification in Paper No. 9, filed April 17, 2002 have overcome the objection to the specification in the previous office action, and the rejection is withdrawn.
4. Amendments to the claims in Paper No. 9 have overcome the objection to the claims in the previous office action, and the rejection is withdrawn.
5. Amendments to the claims in Paper No. 9 have overcome the rejection of the claims under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.

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6. Applicant's arguments with respect to the rejection of claims 1-15 and 19-27 under 35 USC 103 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2314343A (of record).

GB 2314343A taught (see especially the claims) a device with a culture container with a removable cell culture insert with a pair of media supply and discharge (mechanism) lines. The culture container has a level sensor for controlling submerged cell culture and basal culture conditions, where both conditions may be achieved.

9. Claims 1, 3, 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kolodii et al.

Kolodii et al. taught (see the columns 3, 4, 6 and 7) a device with culture containers with removable cell culture insert with a pair of media supply and discharge (mechanism) lines. The

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culture container has level sensors for controlling (switching on and off at predetermined levels) submerged cell culture and basal culture conditions, where both conditions may be achieved.

10. Claims 1, 3-5, 7, 11, 12, 21, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,639,422.

US 4,639,422 taught (see especially the claims) a device with a culture container with a removable cell culture insert with a pair of media supply and discharge (mechanism) lines connected to a common supply line. The culture container has level sensors for controlling (switching on and off at predetermined levels) submerged cell culture and basal culture conditions, where both conditions may be achieved. The level sensors continuously sense the levels of the medium. The container is constructed of sterilizable materials which may be glass.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-7, 11-18, 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of GB 2314343A, Kolodii et al. and US 4,639,422 in view of US 5,612,188.

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The claims are drawn to a device with a culture container with a removable cell culture insert with a horizontal culture surface. The container has a pair of media supply and discharge (mechanism) lines connected to a common supply line. The culture container has level sensors for controlling (switching on and off at predetermined levels) submerged cell culture and basal culture conditions, where both conditions may be achieved. The level sensors continuously sense the levels of the medium. The container is constructed of sterilizable materials which may be glass. There may be multiple culture containers in a horizontal plane connected in series. A programmable controller may control the culture medium target level in a time-dependent manner. Peristaltic pumps are provided for pumping the fluids within the cell culture container system. The culture container may have an exterior housing which may be temperature controlled.

Each of GB 2314343A, Kolodii et al. and US 4,639,422 taught the invention as described above under 35 USC 102.

Each of GB 2314343A, Kolodii et al. and US 4,639,422 did not teach a horizontal culture surface, nor that there may be multiple culture containers in a horizontal plane and a programmable controller which may control the culture medium target level in a time-dependent manner.

US 5,612,188 taught (see especially columns 13-14) the advantageous use of a microprocessor for automatically controlling cell culture conditions such as the media level for optimum growth of the cells in culture, and to control variable conditions (time-dependent)

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during cell growth in multiple growth chambers which may be connected in series and which may be in a horizontal plane. Peristaltic pumps are provided for pumping the fluids within the culture container system. The cell culture containers may be within a temperature controlled housing.

It would have been obvious to one of ordinary skill in the art at the time of filing of the instant application to combine the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 because US 5,612,188 taught the importance of controlling media levels, and cell growth conditions in multiple growth chambers with an automated processor where the multiple chambers may be connected in series, and the cell culture containers may be within a temperature controlled housing.

One of ordinary skill in the art would have been motivated to combine the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 because US 5,612,188 taught the desirable and beneficial use of an automated controller to control cell growth conditions such as media levels to optimize cell growth in multiple growth chambers which may be arranged in series in a horizontal plane within a temperature controlled housing. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188.

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13. Claims 1-18 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 as applied to claims 1-7, 11-18, 21-26 above, and further in view of JP02119772.

The claims are drawn to the invention as described above, and also where the level sensor is a photoelectric device which is height adjustable on a riser, where the level can be adjusted periodically between two levels.

Each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 taught the invention as described above. US 4,639,422 and GB 2314343A each taught the desirable periodic adjustment of media fluid levels in the culture container.

Each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 did not teach a height-adjustable photoelectric level sensor.

JP02119772 taught (see especially pages 4-5 and 12-14) a culturing device which provided for a variable height adjustment of the fluid level photoelectric sensor to control the fluid level of the media in the culture container. The level of the media is sensed and controlled by an automated controller.

It would have been obvious to one of ordinary skill in the art at the time of filing of the instant application to combine the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and with JP02119772 because JP02119772 taught the importance of controlling media levels to maintain optimal growth conditions within the cell growth

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chamber with a variable height adjustment of a fluid level photoelectric sensor to control the fluid level of the media in the culture container.

One of ordinary skill in the art would have been motivated to combine the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and with JP02119772 because JP02119772 taught the desirable and beneficial effects of controlling the liquid level with a variable height liquid level sensor to optimize growth conditions of cells in a culture container. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and with JP02119772.

14. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and with JP02119772 as applied to claims 1-18 and 21-27 above, and further in view of US 5,424,209.

The claims are drawn to the invention as described above, and also where the external housing provides a sealed environment within the housing.

Each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and with JP02119772 taught the invention as described above. US 5,612,188 taught the desirable and beneficial control of the interior environment provided by the housing.

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Each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and with JP02119772 did not teach that the external housing provides a sealed environment within the housing.

US 5,424,209 taught (see especially the summary) a sealed housing surrounding an automated cell culture container system where the housing is sealed to provide protection to the operator of the system from potential harmful exposure to the cell culture system, and that the sealed system also provided desirable and beneficial control of the environment surrounding the cell culture system to optimize culture conditions for growth in the cell culture system. The system provides pumps, heating, fluid level control, and gaseous medium in the interior of the housing, and various control systems to provide for complete management and optimization of growth conditions for the cells in the cell culture containers within the sealed housing.

It would have been obvious to one of ordinary skill in the art at the time of filing of the instant application to combine the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and JP02119772 with US 5,424,209 because US 5,424,209 taught the importance of sealing the exterior housing surrounding the culture container system to protect the operator of the system from harmful effects of the cell culture container system, and that the sealed system also provided desirable and beneficial control of the environment surrounding the cell culture system to optimize culture conditions for growth in the cell culture system.

One of ordinary skill in the art would have been motivated to combine the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and JP02119772 and

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with US 5,424,209 because US 5,424,209 taught the desirable and beneficial protection of the operator of the system from harmful effects of the cell culture container system with a sealed system, and that the sealed system also provided desirable and beneficial control of the environment surrounding the cell culture system to optimize culture conditions for growth in the cell culture system. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of each of GB 2314343A, Kolodii et al. and US 4,639,422 with US 5,612,188 and JP02119772 and with US 5,424,209.

Conclusion

15. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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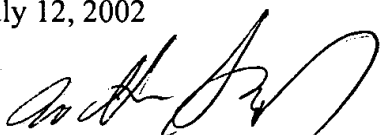
Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

July 12, 2002

A handwritten signature in black ink, appearing to be 'William Sandals', written in a cursive style.